

REMARKS

In an Office Action mailed January 14, 2005, the Examiner imposed final rejections of Claims 1-4, 10-14, 17-19 and 48. Claims 1, 2, 4, 10-14 and 17-19 were rejected under section 112, first paragraph. Claims 3 and 48 were rejected under section 112, second paragraph. The Examiner also objected to claims 5-9 and 49-53 as allegedly depending from a rejected base claim. The Applicants respond to each of the Examiner's rejections or objections below. In view of the amendments noted above and the arguments presented herein, the Applicants respectfully request reconsideration of the merits of this application.

Rejections Under Section 112, First Paragraph

The Examiner rejected Claims 1, 2, 4, 10-14 and 17-19. Applicants respectfully ask the Examiner to again reconsider these rejections. Applicants still do not understand the Examiner's rejection, essentially on the grounds that applicants do not recite all known lipoxxygenase inhibitors in the specification and do not define a structural class of compounds that define lipoxxygenase inhibitors, leading to a requirement for undue experimentation by the skilled person. Applicants respectfully, but strenuously, disagree with the unsupportable limits on the claims proposed by the Examiner.

Independent Claim 1, from which rejected claims 17-19 depend, does not recite a lipoxxygenase inhibitor and, indeed, does not require a lipoxxygenase inhibitor. The Claim recites a reduction in lipoxxygenase activity. Applicants disclose that reduction of lipoxxygenase activity controls body fat and claim in Claim 1 a method commensurate in scope with that disclosure; Claim 1 recites that the activity must be reduced to an extent sufficient to control body fat. The Examiner will agree that the specification (see Detailed Description, especially paragraphs [0017]-[0029]) supports a host of ways to reduce lipoxxygenase activity and provides the skilled person with sufficient guidance to determine whether body fat is controlled. The specification even discloses a test for determining whether body fat is controlled (see paragraph [0017] which states simply that the level of body fat is controlled if the level after treatment IS LOWER THAN BEFORE TREATMENT). A skilled person familiar with operation of lipoxxygenase enzyme surely has the ability to vary a dose of, e.g., a lipoxxygenase inhibitor until such an effect is observed, especially as applicants provide a range of suitable dosages.

On the other hand, independent Claim 2, from which rejected Claims 3, 4 and 10-14 depend, does recite using a lipoxxygenase inhibitor. Had the Examiner imposed an explicit rejection of independent Claim 2 on this basis, applicants would still not understand the Examiner's basis for alleging that the skilled person lacks sufficient guidance to select a lipoxxygenase inhibitor. The applicants seek no protection for a class of structurally novel inhibitors *per se*, nor protection for existing inhibitors. Paragraph [0020] provides guidance for the artisan selecting and using a lipoxxygenase reducing agent, including lipoxxygenase

inhibitors – e.g., having tolerable side effects, being administered in an effective amount, and, optionally, even acting indirectly.

The art of lipoxxygenase inhibitors is old and well developed. Well-known assays permit characterization of compounds as lipoxxygenase inhibitors – simply put, if a compound does not inhibit lipoxxygenase, it is not a lipoxxygenase inhibitor. If it does, it should function in applicant's methods.

It is not as if applicants (or the skilled artisans) have no sense of which compounds will work, or have provided no basis for selecting compounds. Indeed, applicants recite more than 25 structurally distinct compounds having known lipoxxygenase activity, suggesting that the range of suitable inhibitors is great and that selection of a suitable inhibitor is well within the level of ordinary skill. After that, the skilled artisan can surely be counted on to decide how much of such a compound to administer, especially in view of the substantial disclosure of suitable dosages and outcomes in the application (see paragraph [0017], as noted above). Does the Examiner really believe that more than 25 examples of suitable compounds are insufficient?

In short, as it relates to Claim 1, the skilled person reading the claim and the disclosure would understand how to achieve the described control of body fat. While the skilled person might select another lipoxxygenase reducing compound, no further invention, and certainly no undue experimentation, is required. As it relates to Claim 2 and its dependents, the skilled person reading the claims and the disclosure would understand how to achieve the described control of body fat by administering a lipoxxygenase inhibitor. While the skilled person might select a lipoxxygenase inhibitor other than the dozens named, no further invention, and certainly no undue experimentation, is required. Reconsideration is respectfully requested.

Rejections Under Section 112, Second Paragraph

The Examiner rejected Claims 3 and 48. The Examiner maintained a rejection for indefiniteness, asserting that the terms BHA and BHT are tradenames or trademarks. Claim 48 is Claim 3 written in independent form (see Applicant's Response mailed March 17, 2004, wherein it was noted that Claims 48-53 were filed to correspond to pending claims 3 and 5-9, and that upon allowance of the original claims, these added claims would be superfluous).

Applicants strenuously argue in response that the Examiner is incorrect. BHA and BHT are not trademarks or tradenames. Applicants ask the Examiner to take notice of the fact that for at least 35 years these compounds, previously noted to correspond to butyl hydroxyanisole (also spelled hydroxyanisol) and butyl hydroxytoluene, have been known to those skilled in the relevant art as lipoxxygenase inhibitors. See, for example, the list of abbreviations used in Yasumoto, K., et al., "Effect of Phenolic Antioxidants on Lipoxxygenase Reaction," Agr. Biol. Chem. 34:1162, 1163 (1970), submitted on an Information Disclosure Statement. (Applicants understand that the application is under final rejection and that the

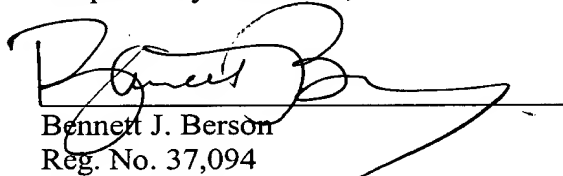
Chem. 34:1162, 1163 (1970), submitted on an Information Disclosure Statement. No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement. Applicants respectfully ask for consideration of this document in an effort to resolve this issue.

Objection

The Examiner objected to Claims 5-9 and 49-53 as being dependent upon rejected base claims. Claims 5-9 remain active, pending further consideration by the Examiner of the arguments presented above in connection with Claim 2. The rejection of claims 49-53 is not understood, as Claims 49 and 53 are in independent form and cannot depend from a rejected base claim, as alleged. Also, Claims 50-52 depend from independent Claim 49. Accordingly, all of Claims 49-53 are already believed to be in condition for allowance. Applicants therefore respectfully request that the Examiner reconsider allowance of Claims 48-53. To avoid any issue of double patenting, the applicants stand ready to cancel either of these sets upon indication of allowable subject matter in the other set. Reconsideration is respectfully requested.

Only the fee set forth in §1.17(p) for the Information Disclosure Statement is believed due in connection with this submission. Please charge the fee to Deposit Account No. 17-0055. If any fee other is due, in this or any subsequent response, please charge the fee to this same Deposit Account. Likewise, no extension of time is believed to be required, but should any extension of time be required, please consider this to be a Petition for the appropriate extension of time and a request to charge the Petition Fee to the same deposit account.

Respectfully submitted,


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